IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor	:	DENYER et al.
Appln. No.	:	09/781,610
Conf. No.:	:	3883
Filed:	:	February 12, 2001
Title:	:	**IMPROVEMENTS IN AND RELATING TO CONTROLLING DRUG DELIVERY APPARATUS**
Group Art Unit	:	3731
Examiner	:	Mendoza, M.
Docket No.	:	011150US2

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January 15, 2011

MS Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
ATTENTION: Board of Patent Appeals and Interferences

APPELLANTS' REPLY BRIEF (37 C.F.R. § 41.41)

This Reply Brief responds to the Examiner's November 15, 2010 Answer in the appeal of the above-captioned application, and is being timely filed within two months of the date of the Examiner's Answer.

The Grounds of Rejection portion of the Examiner's Answer repeats verbatim the rejections made in the April 4, 2010 Final Office Action. Accordingly, Appellants' August 16, 2010 Opening Appeal Brief fully responds to such rejections. The Examiner's Answer also makes several new arguments in the "Response to Argument" section (pp. 7-11 of the Examiner's Answer). Appellants specifically address these new arguments below.

I. Examiner's Answer, ¶ 15: Rejection Of Claim 12 As Anticipated By Gordon

Pages 10-11 of Appellants' Opening Brief explained why Gordon (U.S. Patent No. 4,617,557) failed to disclose or otherwise render obvious, among other things, that "the electronic data carrier further comprises a radio frequency receiver configured to receive nebulizer treatment information from the nebulizer; and [that] the memory is configured to store the nebulizer treatment information received from the nebulizer," as recited in claim 12. The Examiner responds that this recitation reads on the Gordon's "manually swallowed tablet/capsules" because "[t]he appellant has not positively claimed a nebulizer." Examiner's Answer, p. 8, ¶ 15. Appellants specifically traverse the Examiner's assertion because Gordon's manually swallowed tablets/capsules never involve the receipt and storage of "nebulizer treatment information," as explicitly recited in claim 12. Appellants therefore respectfully request the reversal of this rejection for this reason, as well as the additional reasons provided in Appellants' Opening Brief.

II. Examiner's Answer, ¶ 17: Rejection Of Claim 57 As Anticipated By Gordon

Pages 9-10 of Appellants' Opening Brief explained why Gordon failed to disclose or otherwise render obvious, among other things, that "all of the drug in the first container is commonly stored in a single compartment of the first container; and the drug treatment information comprises information indicating that some, but not all, of the drug in the first container should be delivered by the drug delivery device," as recited in claim 57. The Examiner responds that Gordon's entire blister pack 82, including all of its separate capsule compartments, "can be considered as a whole as one compartment." Examiner's Answer, p. 8, ¶ 17. To the contrary, the numerous discrete compartments of Gordon's multi-compartment blister pack cannot reasonably be interpreted to be "as a whole as one compartment." As explained on page 10 of Appellants' Opening Brief, such an interpretation is unreasonable and entirely inconsistent with Gordon, which focuses on keeping separate track of the presence or absence of a tablet/capsule in each individual compartment of the multi-compartment blister package, which Gordon explicitly refers to as "various dosage compartments." Gordon, col. 4, lines 50-51; *see also id.* at FIG. 1. Appellants therefore respectfully request the reversal of this rejection for this reason, as well as the additional reasons provided in Appellants' Opening Brief.

III. Examiner's Answer, ¶ 19: Rejection Of Claims 21, 54, 60, And 61

Claims 21, 54, and 60 were rejected as anticipated by Gordon. Claim 61 was rejected as obvious over Gordon in view of Chartrand (U.S. Patent No. 5,562,550). The Examiner's Answer asserts that:

> As to claims 21, 54, 60, and 61, the appellant argues that Gordon teaches that the transmitter 70 is part of the delivery device and the receiver 74 is part of the data carrier. One of ordinary skill in the art would have found it obvious to reverse the receiver and transmitter, since it has been held that a mere reversal of the essential working parts of a deice involves only routine skill in the art. The function of monitoring the use of the device will not change.

Examiner's Answer, p. 9, ¶ 19. Appellants traverse this assertion for two reasons.

First, claims 21, 54, and 60 were rejected as anticipated by Gordon, not as obvious over Gordon. The Examiner's new obviousness argument cannot support the pending anticipation rejection, which should be reversed for this reason alone.

Second, turning to the substance of the Examiner's argument, the Examiner argues that claims 21, 54, 60, and 61 are obvious over Gordon because it would have been obvious to have switched the relative placement of Gordon's radio frequency transmitter (70) and radio frequency receiver (76). Examiner's Answer, p. 9, ¶ 19. Such a modification would not have been obvious because it would have defeated the entire purpose of Gordon's transmitter and receiver. Specifically, Gordon's transmitter (70) is part of the drug blister package (the alleged drug delivery device) and Gordon's receiver (76) is part of a separate data carrier 64 such that blister package usage information can be transmitted from the blister package to the data carrier 64. *See* Gordon, FIGS. 5-8 and col. 6, lines 47-66. If the positions of the transmitter (70) and receiver (76) were switched, it would be impossible to transmit the blister package usage information from a receiver attached to the blister package to a transmitter attached to the data carrier 64. The proposed modification was therefore nonobvious because it would render Gordon's device inoperable. *See* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."); MPEP 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

Appellants therefore respectfully request the reversal of these rejections for these reasons, as well as the additional reasons provided in Appellants' Opening Brief.

IV. Examiner's Answer, ¶ 24: Rejection Of Claim 17 As Obvious Over Anderson In View Of Gordon

As explained on page 19 of Appellants' Opening Appeal Brief, the proposed combination of Anderson (U.S. Patent No. 5,237,987) in view of Gordon fails to render obvious, among other things, that "the drug delivery device includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery," as recited in claim 17. The Examiner responds that Anderson's and Gordon's teaching of "alarms to warn of improper use" satisfies this combination of recitations. Examiner's Answer, p. 11, ¶ 24. Appellants respectfully traverse the Examiner's assertion for two reasons.

First, an "alarm" does not "prevent delivery" of a drug. Neither reference nor their combination disclose or render obvious a "portion which prevents delivery," as recited in claim 17.

Second, the cited "alarms" in Anderson and Gordon have nothing to do with preventing deliver of a drug "if any of the treatment information indicates that the drug is unsuitable for delivery," as recited in claim 17. The Examiner's cited alarm in Anderson (Anderson, col. 13, lines 13-18) (*see* Examiner's Answer, p. 11, ¶ 24) merely conveys unidentified "information to the user of the ventilator." The Examiner's cited alarm in Gordon (Gordon, col. 2, lines 11-18). (*see* Examiner's Answer, p. 11, ¶ 24) is a non-descript "alarm means." Neither reference discloses that such an alarm has anything to do with preventing deliver of a drug "if any of the treatment information indicates that the drug is unsuitable for delivery," as recited in claim 17.

Appellants therefore respectfully request the reversal of this obviousness rejection of claim 17 for these reasons as well as the reasons provided in Appellants' Opening Appeal Brief.

V. Conclusion

In view of the foregoing and Appellants' August 16, 2010 Opening Brief, Appellants request the reversal of the pending rejections of claims 1, 3, 7, 8, 12, 13, 16-21, 39-41, 44, and 51-63.

Having overcome all objections and rejections, Appellants therefore respectfully request allowance of the present application.

Please charge any fees associated with the submission of this paper to Deposit Account Number 14-1270. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,
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